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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,356	ARKIN ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18-32,34-37,39-128,130-144 and 146-207* is/are pending in the application.

4a) Of the above claim(s) *24, 43-109, 136, and 148-207* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 18-23, 25-32, 34-37, 39-42, 110-128, 130-135, 137-144, and 146-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16, 18-32, 34-37, 39-128, 130-144, and 146-207 are pending. Applicants' cancelled claims 17, 33, 38, 129, and 145. Claims 24, 43-109, 136, and 148-207 are withdrawn from consideration as being drawn to a non-elected invention and/or species. **Claims 1-16, 18-23, 25-32, 34-37, 39-42, 110-128, 130-135, 137-144, and 146-147 are under consideration in the instant office action.** Receipt and consideration of Applicants' amended claim set and remarks/arguments filed on September 14, 2006 is acknowledged.

Specification

The objection to the specification for the improper use of the trademarks LUXIQ® (pg. 3, line 32) and OLUX® (pg. 3, line 32 and pg. 27, lines 5 and 30) **is withdrawn** because Applicants have amended the specification to properly capitalize said trademarks.

Moot Rejections

All rejections in the previous office action mailed on March 17, 2006 of claims 17, 33, 38, 129, and 145 **are moot**, because said claims have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 23, 25-26, 42, 135, 137-138, and 147 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for foamable pharmaceutical compositions, does not reasonably provide enablement for said compositions devoid of a buffering agent **is maintained** for the reasons of record set forth on pages 3-5 of the previous office action mailed on March 17, 2006.

The rejection of claims 1-16, 18-22, 27-32, 34-41, 110-128, 130-134 and 139-144, and 146 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for foamable pharmaceutical compositions, does not reasonably provide enablement for said compositions devoid of a buffering agent **is withdrawn**, per Applicants persuasive arguments (see page 38 in remarks, especially remarks concerning composition I tabulated in the specification).

Response to Arguments

Applicant's arguments filed September 14, 2006 have been fully considered but they are not persuasive. Applicants' traversal is based upon the assertion that composition I on exemplified on page 26 of the specification provides enablement for compositions devoid of a buffer. While this assertion may be correct for the claims not included in this rejection, it is incorrect for claims 23, 25-26, 42, 135, 137-138, and 147, because these claimed compositions inherently comprise a buffer. Firstly, it is noted that claims 25 and 137 require that the pH-adjusting agent be selected from a group consisting solely of weak acids. As explained in the previous office action mailed on March 17, 2006 (see pages 3-5), a weak acid will inherently partially dissociate in the

presence of water or another proton accepting species to form its conjugate base, thus yielding a composition comprising both the weak acid and its conjugate (i.e. a buffer system). Furthermore, the compositions of claims 23 and 135 also inherently comprise a buffer, because these compositions comprise pH-adjusting agents that are weak acids, as evidence by claims, 25-26 and 137-138 which recite that the pH adjusting agent is selected from a group consisting solely of weak acids. It is also noted that exemplified composition II on page 26 of the specification inherently comprises a buffer because it comprises lactic acid. Thus these claimed compositions cannot be devoid of a buffer and the specification does not enable these compositions as being devoid of a buffer. In summary, for the reasons stated above, the Examiner concludes that the claimed compositions of claims 23, 25-26, 42, 135, 137-138, and 147 will inherently comprise a buffer system.

Applicants' arguments, see page 38, filed September 14, 2006, with respect to claims 1-16, 18-22, 27-32, 34-41, 110-128, 130-134 and 139-144, and 146 have been fully considered and are persuasive. The rejection of claims 1-16, 18-22, 27-32, 34-42, 110-128, 130-134 and 139-144, and 146-147 has been withdrawn.

Claims 1-16, 18-23, 25-32, 34, 37, 39-40, 110-128, 130-135, 137-141, and 144 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for foamable pharmaceutical compositions comprising at least one corticosteroid, a non-CFC propellant in a concentration ranging between about 1 weight percentage and about 40 weight percentage of the total weight of the composition, and an acceptable carrier configured, to generate a quick-break foam,

wherein said carrier comprises (i) at least one hydrocarbon alcohol (between about 40 % w/w and 90 % w/w of the total weight of the composition); (ii) at least one fatty alcohol (between about 0.1 % w/w and 20 % w/w of the total weight of the composition); (iii) at least one surface active agent (between about 0.1 % w/w and 60 % w/w of the total weight of the composition); and (iv) water (between about 10 % w/w and 40 % w/w of the total weight of the composition) does not reasonably provide enablement for foamable pharmaceutical compositions comprising at least one corticosteroid, a non-CFC propellant in a concentration ranging between about 1 weight percentage and about 40 weight percentage of the total weight of the composition, and any acceptable carrier. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993),. See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman (230 USPQ 546, 547 (Bd Pat App Int 1986)). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the

invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Breadth of Claims

Applicants' claims 1 and 110, as well as those dependent from claims 1 and 110 are extremely broad because these generically claim a carrier having the property of generating a quick-break foam. Furthermore, Applicants definition of the term "quick-break foam" is extremely broad and encompasses all pharmaceutical foams (i.e. non-crosslinked foams), because said term is defined as, "a foam that collapses when exposed to shearing action [0072]." This definition reads on any pharmaceutical foam, because all non-crosslinked foams (i.e. pharmaceutical foams) will eventually collapse upon application of shear for a long enough period of time. The Examiner is unaware of any pharmaceutical foam that does not collapse when exposed to shearing action for an unspecified amount of time.

Nature of the invention/State of the Prior Art

The instant invention is drawn to foamable pharmaceutical compositions devoid of a buffer and comprising a carrier designed to generate a quick-break foam. Quick-break foams are known from the prior art, for example, from the teachings of Jones et al. (U.S. Patent No. 6,136,920), wherein said foams comprise a quick-break foaming agent, which typically comprise an aliphatic alcohol, water, a fatty alcohol, and a surface-active agent and from the teachings of Tomlinson (WO 85/01876). Quick-break foams ***not*** comprising an aliphatic alcohol, water, a fatty alcohol, and a surface-active agent are not known in the art (i.e. absent a quick-break foaming agent).

Level of One of Ordinary Skill & Predictability/Unpredictability in the Art

The level of a person of ordinary skill in the art is high, with ordinary artisans having advanced medical and/or scientific degrees (e.g. M.D., Ph.D., Pharm. D. or combinations thereof). There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970).

Guidance/Working Examples

The Applicant provides guidance regarding quick-break foams comprising (i) at least one hydrocarbon alcohol (between about 40 % w/w and 90 % w/w of the total weight of the composition); (ii) at least one fatty alcohol (between about 0.1 % w/w and 20 % w/w of the total weight of the composition); (iii) at least one surface active agent (between about 0.1 % w/w and 60 % w/w of the total weight of the composition); and (iv) water (between about 10 % w/w and 40 % w/w of the total weight of the composition). The working examples describe compositions comprising two fatty alcohols (cetyl alcohol [1.1% w/w] and stearyl alcohol [0.5% w/w]), one hydrocarbon alcohol (propylene glycol [0.4% w/w] and ethanol [60.4% w/w]), one surface-active agent (polysorbate 60, 2.0% w/w), and water (31.05% w/w).

In summary, the Examiner concludes that the instant specification does not enable a person or ordinary skill in the art to make and use foamable compositions of claims 1-16, 18-23, 25-32, 34, 37, 39-40, 110-128, 130-135, 137-141, and 144 comprising a carrier configured to generate a quick break foam that lacks (i) at least one hydrocarbon alcohol, (ii) at least one fatty alcohol, (iii) at least one surface-active agent, and (iv) water in the aforementioned amounts disclosed in the specification.

Claims 32 and 140 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the composition of claim 1 for the use in treating a condition selected from the group of conditions listed in claim 32 (e.g. allergic contact dermatitis), does not reasonably provide enablement for curing or preventing a condition, preventing/curing the symptoms of a condition, or preventing the results of a condition and is not enabled for the treatment of all conditions as implied by claim 140. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Although claim 32 claims a foamable composition packaged in a packaging material with printed matter indicating the use of said composition, it implicitly is claiming a method of treating, preventing, or curing any of the 23 conditions identified in print in or on said packaging material.

An analysis based upon the Wands factors is set forth below.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993),. See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman (230 USPQ 546, 547 (Bd Pat App Int 1986)). They include (1) the quantity of

experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Breadth of Claims

Applicants' claims are broad with regards to the composition claimed, because the propellant used and the carrier components are not specified. Applicants claim 32 is claiming the treatment, prevention, and curing of 23 different conditions, whereas Applicants' claim 140 is claiming the treatment, prevention, and condition of any disease or condition. The term eczema (i.e. dermatitis) refers to a broad range of diseases/conditions. The term "acute inflammatory disease" refers to any inflammatory disease that is of a short duration, rapidly progressive, or requiring urgent care, and may include, for example, asthma, pelvic inflammatory disease, peritonitis, sinusitis, pancreatitis, etc.

Nature of the invention/State of the Prior Art

It is known in the prior art that corticosteroids have anti-inflammatory properties and have been used in the to treat inflammation by topical application of compositions containing corticosteroids. The art recognizes that lupus (excluding lupus caused by certain drugs, such as hydralazine, etc.), atopic dermatitis (i.e. atopic eczema), seborrheic dermatitis, psoriasis, granuloma annulare, lichen planus are disorders that have unknown causes (See articles form the Online Merck Manual Home Edition). One cannot prevent a disease or condition that has an unknown cause. The term dermatitis is synonymous with eczema. The art recognizes that contact dermatitis can be prevented

by preventing contact with substances known to cause said condition in a given patient. The habitual scratching of a certain area over a period of time causes lichen simplex chronicus, also known as neuroderamtitis. Allergic reactions are often the cause of papular urticaria (i.e. hives). The cause of dermatitis herpetiformis is an autoimmune reaction to the ingestion of gluten in people sensitive to gluten. The art does not recognize that corticosteroids can prevent contact dermatitis if contact with a substance known to cause this condition in a given patient occurs; prevent dermatitis herpetiformis; prevent allergies resulting in hives (i.e. papular urticaria); or prevent lichen simplex chronicus if a patient continues to scratch the same area habitually. The art does not recognize that corticosteroids can cure keloid scars, lupus, any and all kinds of dermatitis (i.e. any and all kinds of eczema), psoriasis, granuloma annulare, dermatitis herpetiformis, or lichen planus. Furthermore, the art does not recognize that corticosteroids are suitable for the treatment, prevention, and/or curing of all diseases/conditions (e.g. AIDS, cancer, psychotic disorders, elephantitis, Alzheimer's, malaria, bacterial infections, herpes, etc.).

Level of One of Ordinary Skill & Predictability/Unpredictability in the Art

The level of a person of ordinary skill in the art is high, with ordinary artisans having advanced medical and/or scientific degrees (e.g. M.D., Ph.D., Pharm. D. or combinations thereof). There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970).

Guidance/Working Examples

Besides the statement in paragraph [0035] that Applicants' compositions are suitable for the treatment, prevention, or curing of the diseases, conditions, and symptoms of said diseases/conditions, listed in said paragraph and in claim 32, Applicants' provide no guidance. There are no working examples regarding treatment of any disease or condition utilizing Applicants' compositions.

A person of ordinary skill in the art would be required to undergo an undue and burdenensome quantity of experimentation to discover which diseases, if any, can be cured, treated, and/or prevented by Applicants' compositions per the language of claim 140. Regarding claim 32, Applicants' have failed to demonstrate that their invented compositions can prevent any disease or condition, let alone cure the diseases or conditions listed in said claim. At best, Applicants' invented compositions can be used in the treatment of inflammatory diseases, because this is an art-recognized property of corticosteroids.

To emphasize this point the Examiner points Applicants to "Genentech, 108 F.3d at 1366 and *Brenner v. Manson,* 383 U.S. 519, 536, 148 USPQ 689, 696 (1966)" which states,

> "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

In summary, the Examiner concludes that claims 32 and 140, which are implicitly claiming methods of prevention, treatment, and curing, are not enabled for the prevention and curing of any disease, including those listed in claim 32, and are not

enabled for the treatment of all diseases/conditions using Applicants' invented compositions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 42 and 147 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42 and 147 recite the limitation "lactic acid" in lines 14 and 12-13, respectively. There is insufficient antecedent basis for this limitation in the claim. Claims 42 and 147, depend directly from claims 36 and 143, respectively, and depend indirectly from claims 2 and 110, none of the parent claims recite composition comprising lactic acid and/or pH-adjusting agents. Claims 42 and 147 do not claim compositions "further comprising" lactic acid.

Claims 1-16, 18-23, 25-32, 34, 37, 39-42, 110-128, 130-135, 137-144, and 146-147 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements in claims 1-16, 18-23, 25-32, 34, 37, 39-40, 110-128, 130-135, 137-141, and 144 are: the components of the carrier and the amounts of said components that configure the carrier to generate a quick break foam. Paragraphs [0073], [0076], [0081], [0084], and [0085] in the specification clearly would set forth to a person of ordinary skill in the art that for the carriers to have the

property of being able to generate a quick break foam these must comprise (i) at least one hydrocarbon alcohol (between about 40 % w/w and 90 % w/w of the total weight of the composition); (ii) at least one fatty alcohol (between about 0.1 % w/w and 20 % w/w of the total weight of the composition); (iii) at least one surface active agent (between about 0.1 % w/w and 60 % w/w of the total weight of the composition); and (iv) water (between about 10 % w/w and 40 % w/w of the total weight of the composition). It is noted that what constitutes a "quick-break foam" is defined in the specification not by its composition but by its function: a foam that collapses when exposed to shearing action [0072]. Therefore, a person of ordinary skill in the art would be unable to determine from the cited claims, especially not claim 1, what components and amounts of said components of the carrier are required to yield a foamable composition having the claimed property of being a quick break foam.

The remaining claims are rejected for depending upon a rejected claim.

The rejection of claims 22 and 134 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** per Applicants claim amendments removing indefinite language.

The rejection of claims 25-26, 42, and 137-138 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained** for the reasons of record set forth on page 5 of the previous office action mailed on March 17, 2006.

Response to Arguments

Applicant's arguments filed September 14, 2006 have been fully considered but they are not persuasive. Applicants traversal is based upon their remarks in response to the rejection under 35 U.S.C. §112, 1st paragraph and the recitation in claims 26 and 138 reading, "...wherein said acid is the only source of a respective anion in the composition." This is not persuasive. Firstly, it is noted that claims 25 and 137 require that the pH-adjusting agent is selected from a group consisting solely of weak acids. As explained in the previous office action mailed on March 17, 2006 (see pages 3-5), a weak acid will inherently partially dissociate in the presence of water or another proton accepting species to form its conjugate base, thus yielding a composition comprising both the weak acid and its conjugate (i.e. a buffer system). Therefore, despite the wording of the wherein phrase of claims 26 and 138 these compositions will inherently comprise a buffer system and thus cannot be devoid of a buffer.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 19, 21-22, 27-29, 110-113, and 131-134 under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (U.S. Patent No. 5,352,437) **is withdrawn** per Applicants amendments requiring that the amount of non-CFC propellant range between about 1% w/w and about 40% w/w based on the total weight of the composition.

Response to Arguments

Applicant's arguments, see page 40, filed September 14, 2006, with respect to claims 1, 19, 21-22, 27-29, 110-113, and 131-134 have been fully considered and are persuasive. The rejection of claims 1, 19, 21-22, 27-29, 110-113, and 131-134 has been withdrawn.

The rejection of claims 23, 25-26, 135, and 137-138 under 35 U.S.C. 102(b) as being anticipated by Jones et al. (WO 96/27376) **is maintained** for the reasons of record set forth on pages 5 and 7-9 of the previous office action mailed on March 17, 2006 and rearticulated herein above in response to the outstanding rejections of claims 25-26 and 137-138.

The rejection of claims 1-16, 18-19, 21-22, 27-32, 34-37, 39-40, 110-128, 130-131, 133-134, and 139-144 under 35 U.S.C. 102(b) as being anticipated by Jones et al. (WO 96/27376) **is withdrawn**, per Applicants persuasive arguments (see page 42-43 in remarks).

Response to Arguments

Applicant's arguments filed September 14, 2006, as these apply to claims 23, 25-26, 135, and 137-138 have been fully considered but they are not persuasive. Applicants traversal is based upon their remarks in response to the rejection under 35 U.S.C. §112, 1st paragraph and the statements that the compositions are devoid of a buffering agent in paragraphs [0068]-[0069] in the specification. This is not found persuasive, because as discussed above regarding the rejections of claims 25-26 and 137-138 the compositions inherently comprise a buffer. Furthermore, the compositions of claims 23 and 135 also inherently comprise a buffer, because these compositions comprise pH-adjusting agents

that are weak acids, as evidence by claims, 25-26 and 137-138 which recite that the pH adjusting agent is selected from a group consisting solely of weak acids.

Applicant's arguments, see page 40, filed September 14, 2006, with respect to claims 1-16, 18-19, 21-22, 27-32, 34-37, 39-40, 110-128, 130-131, 133-134, and 139-144 have been fully considered and are persuasive. The rejection of claims 1-16, 18-19, 21-22, 27-32, 34-37, 39-40, 110-128, 130-131, 133-134, and 139-144 has been withdrawn.

Claims 1, 18-19, 110-113, 130-131 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al. (U.S. Patent No. 4,668,455).

Applicants claim a foamable pharmaceutical composition comprising (i) at least one corticosteroid, (ii) a non-CFC propellant in a concentration ranging between about 1 weight percentage and about 40 weight percentage of the total weight of the composition, and (iii) an acceptable carrier configured, to generate a quick-break foam.

NOTE: the claimed compositions are not required to be foams, because the term "foamable" is not a positive recitation requiring that the compositions be foams, merely that these have the capacity to be foamed, which is a property of any composition comprising some kind of solvent, propellant, and a molecule having surface active properties. Furthermore, because claim 1 does not set forth the components of the carrier that result in the claimed compositions being able to generate a "quick-break" foam, this limitation is given little weight.

Hansen discloses a composition comprising a steroidal animal repellant steroid (e.g. cortisol or corticosterone or cortisone), solvent, and gaseous blowing agents (i.e.

propellants), including carbon dioxide (CO_2), nitrogen (N_2) and mixtures thereof, wherein the amount of CO_2 and N_2 range from 1-99% by volume N_2 and 99-1% by volume CO_2 (col. 31, lines 3-23 (formulation); col. 19, line 5 through col. 20 line 10 (steroidal animal repellant), and col. 28, lines 44-58 (polymers inherently present in composition)). The composition taught at this particular point in Hansen's process inherently comprises one or more polymers with surfactant properties (e.g. copolymers of ethylene and polar vinyl monomers such as acrylic acid). The term solvent reads on carrier.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 25-26, 42, 135, 137-138, and 147 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones et al. (U.S. Patent No. 6,126,920).

Applicants claim a foamable pharmaceutical composition comprising (i) at least one corticosteroid, (ii) a non-CFC propellant in a concentration ranging between about 1 weight percentage and about 40 weight percentage of the total weight of the composition, (iii) an acceptable carrier configured, to generate a quick-break foam, and (iv) a pH-adjusting agent (e.g. lactic acid).

As was noted above in the rejections under 35 U.S.C. §112, 1st and 2nd paragraphs and §102(b), claims 23, 25-26, 42, 135, 137-138, 147 inherently comprise a buffer, and are thus not devoid of a buffer.

Jones discloses foamable pharmaceutical compositions comprising **(i) a corticosteroid active substance, (ii) a quick-break foaming agent, (iii) a propellant**, and (iv) a buffering agent, wherein **the quick-break foaming agent typically comprises an aliphatic alcohol, preferably in amounts of 40-90% w/w (i.e. a hydrocarbon alcohol), water, preferably in amounts of 10-40% w/w, a fatty alcohol, preferably in amounts of 0.5-10% w/w (e.g. cetyl and stearyl alcohols), surface active agent, preferably in amounts of 0.1-55% w/w (e.g. ethoxylated sorbitan ester, such as Polysorbate 60), and suitable propellants, preferably in amounts of 3-30% w/w, which include propane, butane, octafluoro cyclobutane, and mixtures thereof** (abstract, col. 2, lines 15-62; Example (col. 6, line 64 through col. 7, line 15). Mixtures of cetyl alcohol and stearyl alcohol are particularly preferred (col. 2, lines 28-32). Jones discloses that buffer is necessary to stabilize betamethasone-17-valerate over the less active betamethasone-21-valerate (col. 3, lines 33-51).

Claims 1-16, 18-19, 20-23, 110-118, 119-128, 130-134, and 140 are rejected under 35 U.S.C. 102(e) as being anticipated by Tamarkin et al. (US 2006/027218).

Applicants claim a foamable pharmaceutical composition comprising (i) at least one corticosteroid, (ii) a non-CFC propellant in a concentration ranging between about 1 weight percentage and about 40 weight percentage of the total weight of the composition, and (iii) an acceptable carrier configured, to generate a quick-break foam.

NOTE: the claimed compositions are not required to be foams, because the term "foamable" is not a positive recitation requiring that the compositions be foams, merely that these have the capacity to be foamed, which is a property of any composition

comprising some kind of solvent, propellant, and a molecule having surface active properties. Furthermore, because claim 1 does not set forth the components of the carrier that result in the claimed compositions being able to generate a "quick-break" foam, this limitation is given little weight.

Tamarkin discloses **a foamable vehicle and hygroscopic pharmaceutical compositions thereof**, wherein the foamable carrier includes **about 50% to about 98% w/w of a polar solvent** selected from the group consisting of a polyol and PEG; **0% to about 48% w/w of a secondary polar solvent**; about **0.2% to about 5% by weight of a surface-active agent**; about 0.01% to about 5% w/w of a polymeric agent; and **a liquefied compressed gas propellant at a concentration from about 3% to about 25% w/w** based on the total weight of the composition (title, abstract).

Tamarkin discloses that the foam of the invention is not "quick breaking" (i.e. it does not readily collapse upon exposure to body temperature) and that **sheer-force breakability of the foam is clearly advantageous over thermally induced breakability** since it allows comfortable application and well directed administration to the target area [0108]. Tamarikin's foam is a "quick-break foam" per Applicants' definition in the specification in [0072]: a foam that collapses when exposed to shearing action. Tamarikin's foams have a therapeutically effective amount of an active agent, wherein suitable active agents include **corticosteroids** ([0156] and Example 4-5 (see [0210]-[0211]). The compositions of Examples 4-5, comprised **propylene glycol**, a hydrocarbon alcohol consisting of 3 carbon atoms and two hydroxyl groups, in amount ranging from **43%-58% w/w**. In some embodiments, the compositions may comprise short chain alcohols having one alcohol group and up to 5 carbon atoms in amounts less

than about 5% by weight and in other embodiments the alcohols may be present so long as the ratio of short chain alcohols to polyol is less than 1:4 by weight [0056]. Suitable surfactants for use in the invention include **polysorbates**, such as **polyoxyethylene (20) sorbitan monostearate (TWEEN 60), polyoxyethylene (20) sorbitan monooleate, and polyoxyethylene fatty acid esters** [0066]. The compositions may also optionally contain foam adjuvants, such as fatty alcohols having 15 or more carbons in their chain (e.g. **stearyl alcohol**) [0075]-[0077]. Other additional components may be included in the composition including pH-adjusting agents [0079]; emollients, such as **fatty alcohols, including cetyl alcohols and hexadecyl alcohols** [0080]; **humectants** [0081], preservatives [0082], and skin penetration enhancers [0083] (e.g. octyl alcohol). Suitable propellants include volatile hydrocarbons including **butane, propane, isobutane, fluorocarbon gases, and mixtures thereof** [0084]. The compositions **may contain water up to 25% by weight**, more preferably up to 10% w/w to minimize the probability of degradation of water-sensitive active agents. Other suitable active agents [0132]-[0175] include anti-infectives [0132], analgesics [0139], local anesthetics [0140], etc. In certain embodiments, the compositions may comprise two or more active agents that treat different etiological factors and often result in synergistic effects [0176]-[0177]. It is known that **corticosteroids are stable at acidic pH values and have their maximum stability at a pH of about 4-6** [0177]. Selection of suitable active agents or combination of active agents can yield compositions suitable for the treatment of a variety of disorders/diseases, including dermatological disorders, such as, **eczemas, dermatitis herpetiformis, dermatological inflammation acne, rashes, psoriasis, contact dermatitis, atopic dermatitis**, etc. [0179]. The foamable carriers used may

also comprise polyols (e.g. propylene glycol), which is a hydrocarbon alcohol and known to function as a humectant (Examples 1-2: [0186]-[205]; Example 6: [0212]-[0215]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejections of **(1)** claim 30 under 35 U.S.C. 103(a) as being unpatentable over Nakagawa et al. (USPN 5,352,437) (USPN '437); **(2)** claims 2-16, 18, 20, 25-26, 31, 34-37, 39-42, 114-128, 132, 135, 137-139, and 141-144 under 35 U.S.C. 103(a) as being unpatentable over Nakagawa et al. (USPN 5,352,437) (USPN '437) as applied to claim 30 above, and further in view of Quigley Jr. et al. (U.S. Patent No. 6,075,056); and (3) claims 20, 41-42, 132, and 146-147 under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (WO 96/27376) **are withdrawn** per Applicants amendments requiring that the amount of non-CFC propellant range between about 1% w/w and about 40% w/w based on the total weight of the composition.

Response to Arguments

Applicant's arguments, see pages 43-45, filed September 14, 2006, with respect to claims 2-16, 18, 20, 25-26, 30-31, 34-37, 39-42, 114-128, 132, 135, 137-139, and 141-144 have been fully considered and are persuasive. The rejection of claims 2-16, 18, 20, 25-26, 30-31, 34-37, 39-42, 114-128, 132, 135, 137-139, and 141-144 has been withdrawn.

Claims 27-32, 34, and 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al. (US 2006/0275218) in view of the *Drug Information Handbook* ("DIH"; Lacy, C.; Armstrong, L. L.; Lipsy, R. J.; Lance, L. L. *Drug Information Handbook*, Lexi-Comp, Inc.: Cleveland, 1999-2000, pp 242 and 1098).

NOTE: Tamarkin does not anticipate claims 27-31 because US provisional application 60/492,385 does not provide support for specific corticosteroids.

Applicant Claims

Applicants claim a foamable pharmaceutical composition comprising (i) at least one corticosteroid, (ii) a non-CFC propellant in a concentration ranging between about 1 weight percentage and about 40 weight percentage of the total weight of the composition, and (iii) an acceptable carrier configured, to generate a quick-break foam.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Tamarkin have been set forth above in the instant application. The DIH teaches that **clobetasol propionate is a corticosteroid having anti-inflammatory** properties typically formulated for topical administration to relieve inflammation of moderate to severe corticosteroid-responsive dermatosis (e.g. dermatitis) with **typical dosage amounts being 0.05% by weight** (DIH, pp 242). On page 1098, the DIH teaches several other known corticosteroids (cortisone, **hydrocortisone**, methylprednisolone, prednisolone, prednisone, triamcinolone, **betamethasone**, dexamethasone, and fludrocortisone) and the pharmacological properties of these steroids.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Tamarkin teaches a large number of known corticosteroids these specific corticosteroids are not supported by the disclosure of US provisional application 60/492,385. This deficiency is cured by the teachings of the DIH.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Tamarkin and the DIH, because Tamarkin teaches and exemplifies foamable compositions comprising corticosteroids as the active agent and the DIH teaches specific commercially available corticosteroids. An ordinary skilled artisan would have been motivated to combine the teachings of Tamarkin and the DIH, because both teach corticosteroids and the DIH is a well known reference guide in the pharmaceutical arts regarding commercially known active agents and the pharmacodynamics properties as well as typical dosages and dosage forms of said known actives. For the reasons discussed above, an ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings. Regarding claims 34 and 141, Tamarkin teaches all the claimed components (ethanol, cetyl alcohol, stearyl alcohol, water, and polysorbate 60) are obvious variants thereof (e.g. other polysorbate surfactants). An ordinary skilled artisan would have been motivated to include cetyl alcohol in the exemplified compositions, because it is taught as being an emollient by Tamarikin and emollients are commonly and desirably utilized in topical compositions because these function as moisturizers.

It is noted that Applicants have asserted unexpected results regarding the stability of corticosteroids in foamable compositions devoid of a buffer (see [0068]-

[0069] in the specification). Applicants' data in the specification has been evaluated with regards to Applicants assertion, and the Examiner has concluded that the data provided do not demonstrate unexpected results. Firstly, Applicants' attention is pointed to Figure II, wherein the titration of Applicants' composition II comprising lactic acid (allegedly devoid of a buffer) is compared to the titration of compositions "comprising a buffer" and compositions "containing no acid." Applicants' have asserted throughout prosecution that their compositions do not comprise buffers, however, Fig. II clearly demonstrates that Applicants' exemplified composition II does exhibit buffering because from a pH of 11 to about a pH of 7 it essentially overlaps with the data points of the comparative composition comprising a buffer. After a pH of 7 the titration curves for Applicants' composition II and the "buffered composition" begin to differ. However, this is not evidence that Applicants' composition II is devoid of a buffer, but merely demonstrates that Applicants' exemplified composition II has a different buffering capacity than the comparison composition comprising a buffer.

Regarding Applicants' stability data tabulated on page 28 in Table 1, this data does not demonstrate surprising results. Firstly, the data set appears to be incomplete because there is no data in Table 1 for comparison formulation (e) at zero and 2 months and likewise the data for comparison formulation (d) is incomplete, because there is no data provided at a time of two months. Despite the glaring deficiency of these data one may still compare the relative stability of clobetasol propionate in formulations (a), (b), (d), and (e) by comparing the change in the amount of the clobetasol propionate over time for each formulation. In Applicants' invented composition II (column (a)), the clobetasol exhibits a decrease in concentration of ~6% from a concentration of 0.053%

w/w to 0.050% w/w over a period of 3 months. The comparative composition lacking a pH stabilizer (b) exhibits a decrease in clobetasol concentration of approximately 8% from a concentration of 0.052% w/w at zero months to a concentration of 0.048% w/w at 3 months. A buffered comparative prior art composition in column (d) exhibited a decrease in clobetasol concentration of about 10% over a period of 3 months. There is no data for the buffered prior art composition in column (e) at zero months and 2 months. However, based on the data present in column (e) it appears that the buffered comparison prior art composition only exhibited a decrease in clobetasol concentration of approximately 4% from a concentration of 0.048% w/w to 0.046% w/w (i.e. it had better clobetasol stability than what was observed for Applicants' composition). At this point it is also important to note that Applicants' data appears to exhibit an error in the magnitude of the amount of clobetasol of at least 0.001 % w/w, as evidenced by the values for Applicants' composition at 1 and 2 months of 0.053 and 0.054% w/w. The Examiner has arrived at this conclusion about the minimal error in the presented data because it is physically impossible for a composition to have an increase in the amount of clobetasol present. Given this error, then the % decrease in the concentration of clobetasol propionate for columns (a), (b), (d), and (e) are: 4-7%, 6-9%, 8-12%, and 2-6%, respectively. At best, Applicants' composition exhibited an improvement in the stability of clobetasol propionate over compositions (b) and (d) of 5 and 8% and at worst improved stability of –1 and 4%, respectively. Compared to composition (e), at best Applicants' composition exhibited the same degree of clobetasol propionate degradation and at worst comparison composition (e) exhibited improvement of the stability of clobetasol propionate of 5%. Given the similarity of the different data presented it does

not appear that Applicants' compositions exhibit a surprising result. At best Applicants' composition has demonstrated a slight increase in stability and at worst, worse stability than the prior art composition.

Therefore, the Examiner concludes that the data presented in the specification does not demonstrate unexpected results and this rejection under 35 U.S.C. 103(a) remains proper.

Claims 1-16, 18-23, 25-32, 34-37, 39-40, 110-128, 130-131, 133-135, 137-144, and 146-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (WO 96/27376) ("Jones-WO) or Jones et al. (U.S. Patent No. 6,126,920) ("Jones-US") in view of Tomlinson (WO 85/01876) and McNally et al. (U.S. Patent No. 5,653,961).

NOTE: In favor of compact prosecution, claims 23, 25-26, 135, 137-138, and 147 are included in this rejection in anticipation of Applicants' amendments to the rejected claims.

Applicant Claims

Applicants claim a foamable pharmaceutical composition comprising (i) at least one corticosteroid, (ii) a non-CFC propellant in a concentration ranging between about 1 weight percentage and about 40 weight percentage of the total weight of the composition, and (iii) an acceptable carrier configured, to generate a quick-break foam.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Jones-WO have been set forth on pages 5 and 7-9 of the previous office action mailed on March 17, 2006. In brief summary, Jones-WO teaches **foamable pharmaceutical composition comprising a corticosteroid active substance, a quick break foaming agent (i.e. a mixture of an aliphatic alcohol, water, a fatty alcohol, and a surface-active agent (i.e. surfactant), a propellant**, and a buffering agent. The Examiner would also like to emphasize Jones' teaching on pages 5, line 16 through page 6, line 3 that buffer is needed to stabilize the more active 17-betamethasone valerate ester over the less active 21-betamethasone valerate ester. The teachings of Jones-US have been set forth above in the instant office action. Likewise, the Examiner would like to emphasize Jones-US's teaching that buffer is needed to stabilize the more active betamethasone-17-valerate over the less active betamethasone-21-valerate (col. 3, lines 33-51).

Tomlinson teaches a foamable biocide composition comprising (a) an alcoholic clorhexidine solution, (b) from 0.1-20% w/w of a quick breaking foaming agent [i.e. a mixture of an aliphatic alcohol (40-90% w/w), water (10-40% w/w), fatty alcohol (5-10% w/w), and surface active agent (0.1-15% w/w)], (c) from 3-30% w/w of an aerosol propellant; and optionally (d) a corrosion inhibitor (abstract and page 3, line 28 through page 4, line 2). Preferred formulations are disclosed on page 7.

McNally teaches the desirability of using hydrofluoroalkanes in lieu of chlorofluorocarbon propellants, because at the time of McNally's invention, chlorofluorocarbons were being phased out in favor of propellants, such as hydrofluorocarbons, which were known to be less harmful to the ozone layer (col. 1, lines 25-31).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

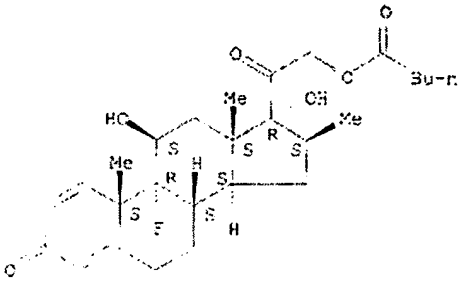
(MPEP §2141.012)

Jones-WO and Jones-US lack the express teaching of foamable compositions comprising a carrier capable of forming a quick-break foam that are devoid of a buffer. This deficiency is cured by the teachings of Tomlinson. McNally is provided to demonstrate that there was a clear motivation throughout the prior art to utilize non-CFC propellants.

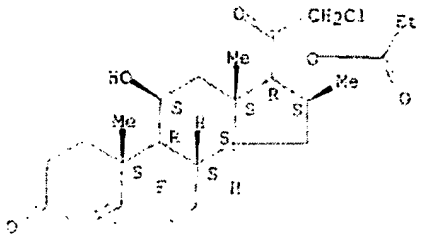
Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Jones-WO or Jones-US with the teachings of Tomlinson and McNally, because the Jones' references and Tomlinson all teach foamable compositions comprising a quick-break foaming agent and McNally teaches that CFC propellants were being phased out in the mid 1990's. It would have been readily apparent to a person of ordinary skill in the art at the time of the instant invention per the teachings of Tomlinson and Jones that buffer is not required to obtain a quick-break foaming agent or foamable compositions containing said agent. An ordinary skilled artisan would have understood that buffer in the foamable compositions taught by either Jones-WO or Jones-US is solely required to stabilize a corticosteroid having active and less active forms (i.e. the 17-valerate ester of betamethasone versus the 21-valerate ester of betamethasone). A person of ordinary skill in the art would also have understood that buffer is not necessary with corticosteroids that do not have both an active and a less active form (e.g. clobetasol propionate), such as, the two

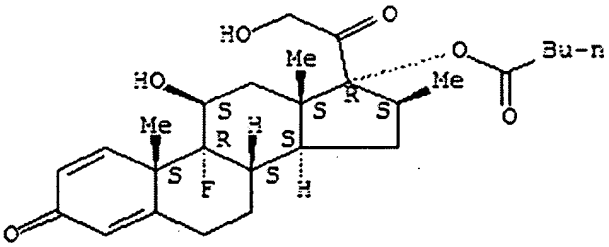
betamethasone esters discussed above, because these other corticosteroids lack a pendant hydroxyl group requiring stabilization with an acidic buffer to prevent intramolecular rearrangement from one ester form to another ester form (see structures depicted below for the two betamethasone esters and clobetasol-propionate).



betamethasone 21-valerate



clobetasol 17-propionate



betamethasone-17-valerate

Regarding the CFC propellant in the foamable compositions of Tomlinson, it would have been obvious to a person of ordinary skill in the art to replace these with other propellants, such as those used by Jones-WO or Jones-US, because it was well known that CFC's were being phased out in favor of chemicals known to be less harmful to the ozone layer. Based on the aforementioned teachings and explanations, an ordinary skilled artisan would have been motivated to obtain foamable pharmaceutical compositions comprising a carrier capable of generating a quick-break foam that lacked a CFC propellant. It would have been obvious to an ordinary skilled artisan that buffer was not required in said compositions wherein the active corticosteroid lacked the ability

to undergo intramolecular rearrangement to a less active form. Said artisan would have had a reasonable expectation of successfully obtaining stable foamable pharmaceutical formulations comprising corticosteroids, such as clobetasol propionate, because it was well known that a corticosteroids are especially stable in a pH range for 4-5, pH-adjusting agents are known in the art (e.g. hydrochloric acid), and adjusting pH by the addition of pH-adjusting agents is well within the capability of a person of ordinary skill in the art. In summary the Examiner concludes that a person of ordinary skill in the art at the time of the instant invention would have found claims 1-16, 18-23, 25-32, 34-37, 39-40, 110-128, 130-131, 133-135, 137-144, and 146-147 *prima facie* obvious over the teachings of the prior art (i.e. Jones-WO, Jones-US, Tomlinson, and McNally) and what was common knowledge in the prior art.

It is noted that Applicants have asserted unexpected results regarding the stability of corticosteroids in foamable compositions devoid of a buffer (see [0068]-[0069] in the specification). Applicants' data in the specification has been evaluated with regards to Applicants assertion, and the Examiner has concluded that the data provided do not demonstrate unexpected results. The Examiner's position regarding Applicants' data and the claim of unexpected results is the same as was articulated above in the instant office action, and is not restated here in favor of brevity.

Therefore, the Examiner concludes that the data presented in the specification does not demonstrate unexpected results and this rejection under 35 U.S.C. 103(a) remains proper.

Double Patenting

The possibility that should claim 32 be found allowable, claim 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof **is moot**, because Applicants' have cancelled claim 33.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 13-14, and 17-19 of copending Application No. 10/850,435 (copending '435).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope. Independent claim 1 of the instant application claims a foamable pharmaceutical composition comprising a corticosteroid, about 1-40% w/w non-CFC propellant, and a carrier configured to

generate a quick-break foam. As discussed above, the claimed composition is not required to be a foam; merely that it has the capability of being manipulated into a foam. A quick-break foam is defined as any foam that collapses when exposed to shearing action. Independent claim 1 of copending '435 claims a foamable pharmaceutical or cosmetic/cosmeceutical composition for topical application comprising urea, at least one propellant, and a pharmaceutically or cosmetically or cosmeceutically acceptable carrier. Dependent claims 13-14 of copending '435 claim compositions further comprising an additional active agent including a steroidal anti-inflammatory agent (e.g. corticosteroids). Dependent claim 16 of copending '435 claims the composition of claim 1 further comprising a variety of excipients/adjuvants/additives, including humectants and pH-adjusting agents. A person of ordinary skill in the art would have found the cited claims of copending '435 prima facie obvious over the cited claims of the instant application because both applications claim foamable compositions comprising a steroidal active agent, propellant, and a pharmaceutically acceptable carrier.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over and claims 1-4, 12-15, and 17-18 of copending Application No. 10/850,461 (copending '461).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope. Independent claim

1 of the instant application claims a foamable pharmaceutical composition comprising a corticosteroid, about 1-40% w/w non-CFC propellant, and a carrier configured to generate a quick-break foam. As discussed above, the claimed composition is not required to be a foam; merely that it has the capability of being manipulated into a foam. A quick-break foam is defined as any foam that collapses when exposed to shearing action. Independent claim 1 of copending '461 claims a pharmaceutical composition comprising urea, ammonium lactate, and an acceptable carrier. The claimed pharmaceutical formulations of copending '461 were obviously intended to include foams, as evidenced by dependent claims 13 and 14, which state the compositions are in the form of a foam. Therefore, the claimed compositions are "foamable"- capable of forming a foam. Dependent claims 17-18 of copending '461 claim compositions further comprising an additional active agent, including a steroidal anti-inflammatory agent. Dependent claim 19 of copending '461 claims a composition of claim 1 further comprising at least one additional component, including a propellant, an emulsifier, pH-adjusting agent, surfactant, etc. Emulsifier and surfactant both read on surface-active agent. A person of ordinary skill in the art would have found the cited claims of copending '461 *prima facie* obvious over the cited claims of the instant application because both applications claim foamable compositions comprising a steroidal active agent, propellant, and a pharmaceutically acceptable carrier and have the same utility (see claim 32 of the instant application and claim 3 of copending '461).

Claims 1 and 32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 13-14, and 17-19 of copending Application No. 10/850,462 (copending '462).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope. Independent claim 1 of the instant application claims a foamable pharmaceutical composition comprising a corticosteroid, about 1-40% w/w non-CFC propellant, and a carrier configured to generate a quick-break foam. As discussed above, the claimed composition is not required to be a foam; merely that it has the capability of being manipulated into a foam. A quick-break foam is defined as any foam that collapses when exposed to shearing action. Independent claim 1 of copending '462 claims a foamable pharmaceutical or cosmetic/cosmeceutical composition for topical application comprising ammonium lactate, at least one propellant, and a pharmaceutically or cosmetically or cosmeceutically acceptable carrier. Dependent claims 13-14 of copending '462 claim compositions further comprising an additional active agent including a steroidal anti-inflammatory agent (e.g. corticosteroids). Dependent claim 16 of copending '462 claims the composition of claim 1 further comprising a variety of excipients/adjuvants/additives, including humectants and pH-adjusting agents. A person of ordinary skill in the art would have found the cited claims of copending '462 prima facie obvious over the cited claims of the instant application because both applications claim foamable compositions comprising a steroidal active agent, propellant, and a pharmaceutically acceptable carrier and have the same utility (see claim 32 of the instant application and claim 3 of copending '462).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 18, and 110-114 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5-10, and 12-13 of copending Application No. 11/194,582 (copending '582).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope. Independent claim 1 of the instant application claims a foamable pharmaceutical composition comprising a corticosteroid, about 1-40% w/w non-CFC propellant, and a carrier configured to generate a quick-break foam. As discussed above, the claimed composition is not required to be a foam; merely that it has the capability of being manipulated into a foam. A quick-break foam is defined as any foam that collapses when exposed to shearing action. Independent claim 1 of copending '582 claims a pharmaceutical or cosmeceutical wash-off mousse shampoo for topical application comprising (a) a cleansing agent (b) at least one active ingredient, and (c) a mousse-forming carrier. Dependent claim 5 of copending '582 claims a composition wherein the active agent includes corticosteroids. The compositions of copending '582 are intended to comprise a propellant and a foam-forming agent, as evidenced by dependent claims 6 and 8, respectively. A person of ordinary skill in the art would have found the cited claims of copending '582 *prima facie* obvious over the cited claims of the instant application because both applications claim foamable compositions comprising a steroidal active

agent, propellant, and a pharmaceutically acceptable carrier and have the same utility (see claim 32 of the instant application and claim 3 of copending '462).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The claims under consideration in the instant office action (i.e. 1-16, 18-23, 25-32, 34-37, 39-42, 110-128, 130-135, 137-144, and 146-147) are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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